NDA 19-880/S-012/S-016

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000

30 APR 2001

Attention: Joseph A. Linkewich, Pharm.D.
Director, Regulatory Science

Dear Dr. Linkewich:

Please refer to your supplemental new drug applications dated August 26, 1999, and April 5, 2000, received August 27, 1999, and April 13, 2000, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paraplatin (carboplatin for injection).

We also acknowledge receipt of your submission dated May 3, 2000.

Supplemental application 012 provides for the addition of a "Geriatric Use" subsection as compliant with 21 CFR 201.57(f)(10), specifically paragraphs (ii)(C) and (iii)(A).

Special Supplement Changes Being Effected 016 (with FPL) provides for an addition to the ADVERSE REACTIONS section of the insert that is based on events identified from ongoing post-marketing surveillance. This supplement also provides for the removal of all references other than those pertaining to the handling of antineoplastic agents.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

In the **PRECAUTIONS** section, **Geriatric Use** subsection, we recommend the following changes:

1. The 889 patients referenced should be 789 patients.

2. Regarding the following statement:

   "In a combined database of 1942 patients (414 were ≥ 65-years of age), that received single agent carboplatin for different tumor types, a similar incidence of adverse events was seen in elderly and non-elderly patients."

It is requested that the sponsor provide the source of this information, i.e., specific details about the database, whether FDA has already reviewed this information, and specify ages instead of using the terms “elderly and non-elderly”.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package inserts submitted August 26, 1999, and April 5, 2000). These revisions are terms of the approval of these applications

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 19-880/S-012/S-016." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christy Wilson, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research